



EXHIBIT 1



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EXHIBIT 2



CAUSE NO. D140013C

VIRGINIA K. TREADWELL,
Plaintiff

vs.

BLUE CROSS AND BLUE
SHIELD OF TEXAS,
Defendant

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IN THE DISTRICT COURT

391st JUDICIAL DISTRICT

TOM GREEN COUNTY, TEXAS

FILED FOR PETITION
2014 JAN 16 PM 10:22
SHERI WOODFIN, DISTRICT CLERK
TOM GREEN COUNTY, TEXAS

ORIGINAL PETITION AND APPLICATION FOR INJUNCTIVE RELIEF

TO THE HONORABLE COURT:

Virginia Treadwell, Plaintiff, files this Original Petition and Application for Injunctive Relief against Blue Cross and Blue Shield of Texas, Defendant, and in support thereof would respectfully show the Court as follows:

I. DISCOVERY CONTROL PLAN

1. Plaintiff intends to conduct discovery under Level 3 of Texas Rule of Civil Procedure 190.

II. PARTIES

2. Virginia Treadwell, Plaintiff, is a resident of Texas.
3. Blue Cross and Blue Shield of Texas, Defendant, is a business registered to do business in the state of Texas. Defendant may be served at Corporation Service Company, 211 East 7th Street Suite 620, Austin, TX 78701-3218.

III. JURISDICTION AND VENUE

4. This court has jurisdiction over Defendant in that Defendant is a Texas resident and the amount in controversy is within the jurisdictional limits of this court.
5. Venue of this action is proper in Tom Green County, Texas pursuant to Tex. Civ. Prac. & Rem Code Ann. §15.002 in that all of a substantial part of the events or omissions giving rise to the claims herein occurred in Tom Green County, Texas.

IV. FACTS

6. For the past twenty-one months, Plaintiff has been receiving IVIG infusions and Defendant has approved these infusions and has paid for these infusions. Plaintiff's last infusion was Monday, December 30, 2013. Because of Defendant's arbitrary denial, Plaintiff has now missed least two infusions on January 6, 2014 and January 13, 2014.

7. All of a sudden, Defendant stopped covering this treatment. On December 27, 2013, Defendant sent Plaintiff a letter stating preauthorization of the extension of extended care benefits had been

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denied. See attached letter from Defendant, dated December 27, 2013, consisting of two pages. See also attached letter from defendant, dated March 30, 2013, consisting of three pages, which is the most recent approval over the twenty-one month history of Defendant improving such infusions.

8. Defendant stated that the extended care extension was not medically necessary because services are experimental or investigational. The clinical basis for this determination was that IVIG has not been approved by the U.S. Food and Drug Administration for the treatment of Sicca/Sjogren's Syndrome.

9. Defendant has been paying for IVIG to treat Plaintiff's Sjogren's syndrome and Autoimmune Autonomic Neuropathy for almost two years. Defendant has approved IVIG ordered from the same doctor and for the same diagnosis in the past. Defendant is now denying coverage for the same treatment, ordered by the exact same physician, and for the same diagnosis that was already covered.

10. Plaintiff's physician, Dr. Robert J Meador Jr had a peer review with a Rheumatologist who worked for Defendant and Defendant persisted in their denial. Dr. Meador then filed an appeal with Defendant and Defendant still persisted in their denial. See attached letter from Dr. Robert J Meador Jr MD, dated December 30, 2013, consisting of three pages.

11. January 13, 2014, Plaintiff overnighted a package consisting of 400 pages of medical literature, case studies, and a letter to Defendant requesting an independent review. Once the Texas Department of Insurance receives the package and request for an independent review from Defendant, they will assign it to an Independent Review Organization. The Independent Review Organization then has 20 days to respond. Plaintiff will miss, at the very least, three more weekly treatments during this period, and will continue to suffer immediate, irreparable harm in the form of nerve damage and will continue to deteriorate.

12. Since Defendant has denied Plaintiff further treatments, she has suffered irreparable harm. This harm is occurring today, at this very moment, as you read this. Plaintiff has slowly begun to regress again. Plaintiff fell this past week after she began to experience extreme dizziness and confusion, along with nerve, muscle and joint pain. Plaintiff blacked out and woke up on the ground with a black eye and scrapes, scratches, and skin missing from her face. Please see the attached two pictures. Dr. Robert Meador has increased the dose of Plaintiff's Methotrexate three times since Defendant's denial but this has not helped. See the attached affidavits detailing the irreparable harm Plaintiff is currently suffering, and will continue to suffer, unless this Court grants this Temporary Restraining Order.

13. Plaintiff and Plaintiff's family's life changed about three years ago when Plaintiff went in the hospital with an unexplained, but life-threatening virus. The cause was never determined, but the effects were permanent. Plaintiff went from a healthy 38 year-old women, actively involved in her children's lives and society, to being eventually diagnosed with debilitating Sjogren's, Gastroparesis, and Autonomic Neuropathy, along with many diagnosis that accompany these.

14. Since Plaintiff started IVIG, Plaintiff has gone from an unproductive member of society- unable to drive or work, unable to participate in her 11 and 13 year-olds' lives, unable to eat solid foods, bedridden most of the time, suffering from daily diarrhea and dizziness, low blood



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pressure and tachycardia, having bouts of cognitive confusion that could last for days at a time, unable to drive for five months, running a low-grade fever with no explanation daily, having almost unbearable joint pain, wearing wrist splints and alternating ice and heat on her wrists for carpal tunnel; to a functioning mother and wife, able again to participate for the most part in her children's lives.

15. Sjögren's syndrome is an autoimmune disease. The primary mechanism known to occur in Sjögren's is damage to exocrine glands, such as tear glands and salivary glands. Some patients experience severe extra-glandular manifestations, that can result in damage to one or more organs and severe neurological damage.

16. Patients with the more traditional dryness and joint symptoms are usually treated symptomatically, with eyes drops and pain medications. However, Plaintiff suffers from the more serious form of Sjögren's, who have extra-glandular manifestations and severe neurological damage, have to be treated early and aggressively with IVIG and immunosuppressants.

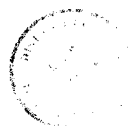
17. Plaintiff is on an immunosuppressant, methotrexate, and she is closely monitored with frequent blood tests. Methotrexate is used to treat cancer or certain other conditions that are very severe and that cannot be treated with other medications. Methotrexate may cause very serious, life-threatening side effects. It can cause a decrease in the number of blood cells made by your bone marrow, a decrease the activity of the immune system, liver damage, lung damage, damage to the lining of the mouth, stomach, or intestines, and it may cause patients to develop serious infections.

18. The incidence of developing lymphoma is higher than the norm in patients with Sjogren's syndrome. It is estimated that about 5-10% of patients with primary Sjogren's syndrome develop lymphoma. One of the risk factors that has been identified for the development of lymphoma is peripheral neuropathy, which is estimated to only occur in 1.8% of primary Sjögren's patients. Plaintiff suffers from peripheral neuropathy as another severe complication of her Sjogren's syndrome

19. Plaintiff has also been diagnosed with autoimmune autonomic neuropathy. The degree and type of autonomic system involvement varies extensively. In some patients, the degree of autonomic dysfunction may be subclinical or clinically irrelevant; in others, symptoms may be disabling. Autonomic neuropathy is a group of symptoms that occur when there is damage to the nerves that manage every day body functions such as blood pressure, heart rate, bowel and bladder emptying, and digestion.

20. Autonomic nerves are responsible for controlling body functions that occur outside our control, such as breathing, digestion, heart rate, and blood pressure. Neuropathy results when nerve cells, or neurons, are damaged or destroyed. Autonomic neuropathy involves damage to the nerves that run through a part of the peripheral nervous system. The peripheral nervous system includes the nerves used for communication to and from the brain and spinal cord (central nervous system) and all other parts of the body, including the internal organs, muscles, skin, and blood vessels.

21. Damage to the autonomic nerves affects the function of areas connected to the problem nerve.



22. Plaintiff suffers from severe autonomic neuropathy. It has affected all areas of her autonomic nervous system. Damage to the nerves of her gastrointestinal tract makes it harder to move food during digestion (decreased gastric motility, ie gastroparesis). She also suffers from episodic diarrhea. Plaintiff has sluggish pupil reaction, making it difficult to adjust from light to dark and causing problems with driving at night. Plaintiff often has blurring and then graying of vision, and difficulty with focusing. Plaintiff's cardiovascular system has been damaged, causing heart palpitations, tachycardia, nausea, tremulousness, light-headedness, visual blurring, tinnitus, headache, chest pain, and shortness of breath. Damage to the nerves supplying blood vessels causes problems with Plaintiff's blood pressure and body temperature. She has decreased sweating, which affects her body's ability to regulate body temperature. Plaintiff has frequent dizziness upon standing caused by a drop in blood pressure. She suffers from hair loss and burning, tingling and numbness in her extremities.

23. Autonomic neuropathy affects the nerves that regulate vital functions, including the heart muscle and smooth muscles.

24. Many cases of autonomic neuropathy have a gradually progressive course, leading to a poor outcome. Patients with severe autonomic neuropathy are at risk for sudden death secondary to cardiac dysrhythmia, as has been documented in Guillan Barre Syndrome and diabetic neuropathy.

.V. BREACH OF CONTRACT

25. On or about June 1, 2009 the defendant agreed to insure, for a consideration, the plaintiff with health insurance .

26. On or about December 27, 2013, while the insurance was still in full force and effect, Defendant refused to allow Plaintiff to continue with treatment, IVIG, that Defendant had approved for the twenty-one months prior to the Defendant's refusal of December 27, 2013.

27. In refusing to allow plaintiff's treatment under the policy, the defendant has breached the terms of the agreement between defendant and plaintiff.

28. Plaintiff asks for specific performance, in that this Court orders that Defendant Blue Cross and Blue Shield of Texas, its agents, employees, servants and independent contractors are ordered to continue to provide Virginia Treadwell with the treatment and support which is currently being provided as per the current medications and physicians orders until further order of the court. we will be able to continue to provided IVIG and nursing for Plaintiff and bill Blue Cross and Blue Shield of Texas for these services.

VI. PROMISSORY ESTOPPEL

29. The Defendant made a promise to the Plaintiff.

30. The Defendant could foresee that the Plaintiff would rely on the promise.

31. The Plaintiff did substantially rely on the promise to her detriment.

32. Injustice can be avoided only by the legal enforcement of the promise against the Defendant.



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VII. FRAUD

- 33. The Defendant made a material representation to the Plaintiff that was false.
- 34. When the material representation was made, the Defendant knew that the material representation was false, or made the material representation recklessly without any knowledge of its truth and as a positive assertion.
- 35. The Defendant made the material representation with the intent that it should be acted upon by the Plaintiff;
- 36. The Plaintiff acted in reliance upon the representation.
- 37. The Plaintiff suffered injury or damage.

VIII. INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

- 38. The Defendant acted intentionally or recklessly.
- 39. The Defendant's conduct was extreme and outrageous.
- 40. The acts of the Defendant caused the Plaintiff to suffer emotional distress.
- 41. The emotional distress suffered by the Plaintiff was severe.

IX. BAD FAITH

- 42. The Defendant failing to promptly and thoroughly investigate a claim.
- 43. The Defendant unreasonably denied benefits to a claim.
- 44. The Defendant used unreasonable interpretations in translating policy language

X. TEXAS DECEPTIVE TRADE PRACTICES LAW

- 45. This suit is brought against Defendant for violations of the Texas Deceptive Trade Practices -- Consumer Protection Act, TEX. BUS. & COM. CODE § 17.41, *et seq.* (the "DTPA") and TEX. INS. CODE § 541.001, *et seq.* (formerly TEX. INS. CODE art. 21.21).

XI. PRACTICES ACT NOTICE

- 46. Defendant has been notified in general of the alleged unlawful conduct described below in accordance with TEX. BUS. & COM. CODE § 17.47(a).

XII. ACTS OF AGENTS

- 47. An allegation that Defendants or a Defendant engaged in any act or practice means:
 - a. that a Defendant performed, authorized or participated in the act or practice; or

b. that one or more of the Defendant's officers, agents, representatives or employees performed or participated in the act or practice on behalf of and under the authority or direction of the Defendant.

XIII. TRADE AND COMMERCE

48. Defendant is a "person," as defined by the DTPA § 17.45(3) and TEX. INS. CODE § 541.002, and has, at all times as described below, engaged in conduct that constitutes "trade" and "commerce," as those terms are defined by § 17.45(6) of the DTPA, and also in conduct that constitutes the "business of insurance" in Texas under TEX. INS. CODE Chapter 541. The unlawful conduct of Defendant has affected and continues to affect persons in the State of Texas.

XIV. TEXAS DECEPTIVE TRADE PRACTICES -- CONSUMER PROTECTION ACT VIOLATIONS

49. Sections X through XIII are incorporated herein by reference. Defendant has violated and continues to violate TEX. BUS. & COM. CODE § 17.41, *et seq.* by engaging in one or more of the following acts or practices:

- a. engaging in false, misleading, or deceptive acts or practices in the conduct of trade and commerce, in violation of TEX. BUS. & COM. CODE § 17.46(a);
- b. representing that its goods or services have characteristics, uses or benefits which they do not have, in violation of TEX. BUS. & COM. CODE § 17.46(b)(5); and
- c. representing that an agreement confers or involves rights, remedies, or obligations which it does not have or which are prohibited by law, in violation of TEX. BUS. & COM. CODE § 17.46(b)(12).

XV. TEXAS INSURANCE CODE VIOLATIONS

50. Sections IV through X are incorporated herein by reference. Defendant has violated TEX. INS. CODE Chapter 541 by engaging in one or more of the following acts or practices:

- a. Engaging in unfair or deceptive acts or practices in the business of insurance, in violation of TEX. INS. CODE § 541.003;
- b. Making, issuing, or circulating, or causing to be made, issued or circulated, a statement misrepresenting the benefits or advantages of credit insurance policies, in violation of TEX. INS. CODE § 541.051(1)(B);
- c. Making, publishing, disseminating, circulating or placing before the public, or causing, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, a statement containing an untrue, deceptive, or misleading assertion, statement, representation or statement regarding the business of insurance, in violation of TEX. INS. CODE § 541.052;
- d. Making an untrue statement of material fact in violation of TEX. INS. CODE § 541.061(1);
- e. Failing to state a material fact necessary to make the other statements made not

misleading, considering the circumstances under which the statements were made, in violation of TEX. INS. CODE § 541.061(2);

f. Making a statement in such manner as to mislead a reasonably prudent person to a false conclusion of a material fact, in violation of TEX. INS. CODE § 541.061(3); and

h. Making a material misstatement of law in violation of TEX. INS. CODE § 541.061(4).

XVI. TEXAS ADMINISTRATIVE CODE VIOLATIONS

51. Sections IV through XI are incorporated herein by reference. Defendant has engaged in trade practices in the business of insurance which are unfair or deceptive, in violation of 28 TEX. ADMIN. CODE § 21.203.

XVII. REQUEST FOR INJUNCTION

52. Because the Defendant has engaged in the unlawful acts and practices described above, Defendant has violated the law as set forth herein. Unless restrained by this Honorable Court, Defendant may continue to violate the laws of the State of Texas and cause additional injury, loss and damage to Plaintiff.

53. Plaintiff respectfully requests that after notice and hearing this Court issue a permanent injunction restraining and enjoining Defendant, Blue Cross and Blue Shield of Texas, its agents, employees, servants and independent contractors, as follows:

a. Defendant must refrain from denying coverage for IVIG therapy for Plaintiff and to continue to provide Virginia Treadwell with the treatment and support which is currently being provided as per the current medications and physicians orders until further order of the court.

b. Defendant must refrain from cancelling the Plaintiff's insurance policy until the Defendant negotiates with Plaintiff in good faith and provides coverage for IVIG.

XIV. CIVIL PENALTIES AND RESTITUTION

54. In addition, Plaintiff, respectfully requests that this court:

a. Adjudge against the Defendant civil penalties in the amount of not more than \$20,000 per violation of the DTPA, pursuant to TEX. BUS.&COM.CODE § 17.47(c);

b. Adjudge against Defendant civil penalties of up to \$10,000 per violation of Chapter 541 of the Texas Insurance Code, and the administrative rules promulgated under thereunder, pursuant to TEX. INS. CODE § 541.204; and

c. Adjudge compensatory, punitive and treble damages against the Defendant.

XV. TEMPORARY RESTRAINING ORDER, TEMPORARY AND PERMANENT INJUNCTION

55. Plaintiff has reason to believe and does believe that, while this case is pending, Defendant will

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persist in refusing to allow Plaintiff to receive IVIG. Plaintiff will continue to be irreparably harmed because of Defendant's conduct, for which Plaintiff will have no adequate remedy at law. Plaintiff therefore requests that this Court enter a temporary injunction against Defendant, Blue Cross and Blue Shield of Texas, its agents, employees, servants and independent contractors are ordered to continue to provide Virginia Treadwell with the treatment and support which is currently being provided as per the current medications and physicians orders until further order of the court, we will be able to continue to provided IVIG and nursing for Mrs. Treadwell and bill Blue Cross and Blue Shield of Texas for these services.

56. At the conclusion of this case, Plaintiff requests the Court to issue a permanent injunction compelling Defendant to refrain from denying coverage for IVIG therapy for Plaintiff and to continue to provide Virginia Treadwell with the treatment and support which is currently being provided as per the current medications and physicians orders until further order of the court. In addition, Plaintiff requests the court to issue a permanent injunction compelling Defendant to refrain from cancelling the Plaintiff's insurance policy until the Defendant negotiates with Plaintiff in good faith and provides coverage for IVIG.

XVI. ATTORNEY'S FEES AND INTEREST

57. Because of Defendant's conduct, Plaintiff, an Attorney at law, and Charles King, Attorney at Law, will have to prosecute Plaintiff's claims in this case. Plaintiff hereby seeks to recover from Defendant her reasonable and necessary attorneys' fees incurred in the prosecution of this lawsuit. Plaintiff further seeks pre- and post-judgment interest as allowed by law.

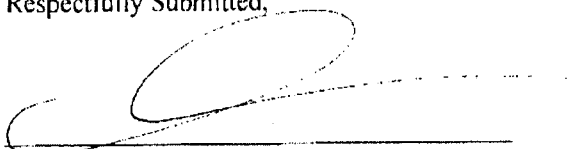
XVII. CONDITIONS PRECENT

58. All conditions precedent have occurred or have been performed by Plaintiff or have been waived by Defendant to entitle Plaintiff to all the relief sought by the Plaintiff herein.

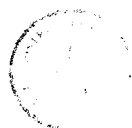
XVIII. PRAYER

WHEREFORE, PREMISES CONSIDERED, Plaintiff, respectfully prays that Defendant be served with citation as required by law and, upon the trial hereof, that this court grant judgment to Plaintiff against Defendant, Blue Cross, for all relief requested herein and to all other relief, both general and special, at law or in equity, to which Plaintiff may show herself entitled.



Respectfully Submitted,



Virginia Treadwell, Attorney for Plaintiff
State Bar No. 24011817
5476 fm 2335
Christoval, TX 76935
(325) 896-2505
(325) 896-2507 fax



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Charles W King, Co-Counsel for Plaintiff
State Bar No. 11436525
101 S Park
San Angelo, TX 76901
(325) 227-6536 phone
(325) 227-6537 fax

VERIFICATION

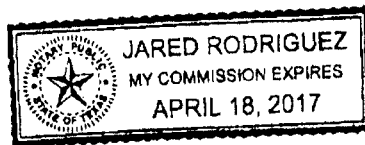
STATE OF TEXAS)
)
COUNTY OF TOM GREEN)

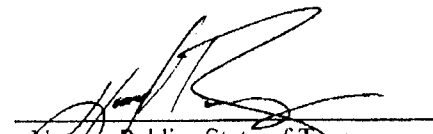
BEFORE ME, the undersigned authority, on this day personally appeared Virginia Treadwell, who upon her oath deposed and stated that she has read the foregoing Original Petition and Application for Injunctive Relief, and that, except for those statements made on information and belief, the statements contained therein are true and correct and within her personal knowledge.



VIRGINIA TREADWELL,
PLAINTIFF

SWORN TO this 16th day of January, 2014.





Notary Public, State of Texas

CAUSE NO. D1400/3C

VIRGINIA K. TREADWELL,
Plaintiff

vs.

BLUE CROSS AND BLUE
SHIELD OF TEXAS,
Defendant

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IN THE DISTRICT COURT

391st JUDICIAL DISTRICT

TOM GREEN COUNTY, TEXAS

AFFIDAVIT OF VIRGINIA TREADWELL

Before me, the undersigned notary, on this day personally appeared, VIRGINIA TREADWELL, a person whose identity is known to me. After I administered an oath to her, upon her oath she said:

1. "My name is VIRGINIA TREADWELL. I am over 18 years of age, of sound mind, and capable of making this affidavit. The facts stated in this affidavit are within my personal knowledge and are true and correct.
2. "For the past twenty-one months, I have been receiving IVIG infusions and Blue Cross and Blue Shield of Texas has approved these infusions and has paid for these infusions. My last infusion was Monday, December 30, 2013. Because of Blue Cross and Blue Shield of Texas's arbitrary denial, I have now missed least two infusions on January 6, 2014 and January 13, 2014.
3. "All of a sudden, Blue Cross and Blue Shield of Texas stopped covering this treatment. On December 27, 2013, Blue Cross and Blue Shield of Texas sent me a letter stating preauthorization of the extension of extended care benefits had been denied. Dr. Meador and I were shocked.
4. "Blue Cross and Blue Shield of Texas stated that the extended care extension was not medically necessary because services are experimental or investigational. The clinical basis for this determination was that IVIG has not been approved by the U.S. Food and Drug Administration for the treatment of Sicca/Sjogren's Syndrome.
5. "Blue Cross and Blue Shield of Texas has been paying for IVIG to treat my Sjogren's syndrome and Autoimmune Autonomic Neuropathy for almost two years. Blue Cross and Blue Shield of Texas has approved IVIG ordered from the same doctor and for the same diagnosis in the past. Blue Cross and Blue Shield of Texas is now denying coverage for the same treatment, ordered by the exact same physician, and for the same diagnosis that was already covered.
6. "My physician, Dr. Robert J Meador Jr had a peer review with a Rheumatologist who worked for Blue Cross and Blue Shield of Texas and they persisted in their denial. Dr. Meador then filed an appeal with Blue Cross and Blue Shield of Texas and they still persisted in their denial.

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7. "January 13, 2014, Plaintiff over nighted a package consisting of 400 pages of medical literature, case studies, and a letter to Blue Cross and Blue Shield of Texas requesting an independent review. Once the Texas Department of Insurance receives the package and request for an independent review from Blue Cross and Blue Shield of Texas, they will assign it to an Independent Review Organization. The Independent Review Organization then has 20 days to respond. I will miss, at the very least, three more weekly treatments during this period, and will continue to suffer immediate, irreparable harm in the form of nerve damage and will continue to deteriorate.

8. "Since Blue Cross and Blue Shield of Texas has denied my further treatments, I have suffered irreparable harm. This harm is occurring today, at this very moment, as you read this. I have slowly begun to regress again. I fell this past week after I began to experience extreme dizziness and confusion, along with nerve, muscle and joint pain. I blacked out and woke up on the ground with a black eye and scrapes, scratches, and skin missing from her face.

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11. "Since I started IVIG, I have gone from an unproductive member of society- unable to drive or work, unable to participate in my 11 and 13 year-olds' lives, unable to eat solid foods, bedridden most of the time, suffering from daily diarrhea and dizziness, low blood pressure and tachycardia, having bouts of cognitive confusion that could last for days at a time, unable to drive for five months, running a low-grade fever with no explanation daily, having almost unbearable joint pain, wearing wrist splints and alternating ice and heat on my wrists for carpal tunnel; to a functioning mother and wife, able again to participate for the most part in my children's lives.

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and that cannot be treated with other medications. Methotrexate may cause very serious, life-threatening side effects. It can cause a decrease in the number of blood cells made by your bone marrow, a decrease the activity of the immune system, liver damage, lung damage, damage to the lining of the mouth, stomach, or intestines, and it may cause patients to develop serious infections.

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18. "Damage to the autonomic nerves affects the function of areas connected to the problem nerve. I suffer from severe autonomic neuropathy. It has affected all areas of my autonomic nervous system. Damage to the nerves of my gastrointestinal tract makes it harder to move food during digestion (decreased gastric motility, ie gastroparesis). I also suffer from episodic diarrhea. I have sluggish pupil reaction, making it difficult to adjust from light to dark and causing problems with driving at night. I often has blurring and then graying of vision, and difficulty with focusing. My cardiovascular system has been damaged, causing heart palpitations, tachycardia, nausea, tremulousness, light-headedness, visual blurring, tinnitus, headache, chest pain, and shortness of breath. Damage to the nerves supplying blood vessels causes problems with my blood pressure and body temperature. I have decreased sweating, which affects her body's ability to regulate body temperature. I have frequent dizziness upon standing caused by a drop in blood pressure. I suffer from hair loss and burning, tingling and numbness in her some of my extremities.

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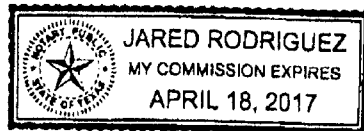


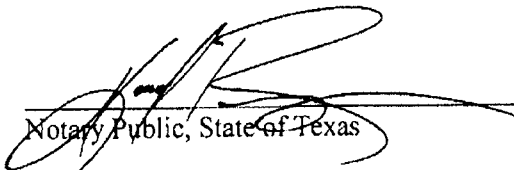
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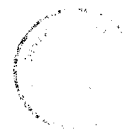
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VIRGINIA TREADWELL

SIGNED under oath before me on January 16th, 2014.




Notary Public, State of Texas



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BlueCross BlueShield
of Texas

December 27, 2013

Virginia Treadwell
5476 FM 2335
Christoval, TX 76935-3304

Identification #: 903574434
Group #: 000940
Patient's D.O.B.: 1971
Group Name: Blue Cross Blue
Shield of Texas
Denial Reference #: 13074AABLJ

Dear Virginia Treadwell:

This letter is written notification that preauthorization of the extension of extended care benefits has been denied as described below.

Patient: Virginia Treadwell
Referring Provider: Robert J. Meador, MD
Servicing Provider: Central Line Infusion, LTD

Service	Status	Units/Visits	Current Date Span
J1569	denied	60	01/01/2014 – 12/31/2014
S9338	denied	1	01/01/2014 – 12/31/2014
S9374	denied	1	01/01/2014 – 12/31/2014
J1200	denied	1	01/01/2014 – 12/31/2014
J7030	denied	1	01/01/2014 – 12/31/2014
J2550	denied	1	01/01/2014 – 12/31/2014
J1100	denied	1	01/01/2014 – 12/31/2014
99601	denied	1	01/01/2014 – 12/31/2014

Our review determined that the extended care extension is not medically necessary based on the following principal reason(s):

- Services are experimental or investigational.

The clinical basis for this determination is as follows:

- The request for continuation of home infusion of Intravenous Immunoglobulin (IVIG) therapy per CPT codes J1569 (Injection, immune globulin, (Gammagard liquid), intravenous, non-lyophilized, (for example, liquid), 500 milligrams), S9338 (Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment), S9374 (Home infusion therapy, hydration therapy; one liter per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment), J1200 (Injection, diphenhydramine hydrochloride, up to 50 milligrams), J7030 (Infusion, normal saline solution, 1000 cubic centimeters), J2550 (Injection, promethazine hydrochloride, up to 50 milligrams), J1100 (Injection, dexamethasone sodium phosphate, 1 milligram) and 99601 (Home infusion/specialty drug administration, per visit (up to 2 hours)) has been denied as experimental, investigational and unproven. For treatment of Sicca/Sjogren's Syndrome, IVIG has not been approved by the U.S. Food and Drug Administration (FDA). Also, the available peer reviewed scientific literature has not found IVIG treatment to be safe, effective and durable. Therefore, the request for continuation of IVIG therapy for treatment of Sicca/Sjogren's Syndrome is denied as experimental, investigational and unproven.

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December 27, 2013
Virginia Treadwell
903574434

The criteria used in making the adverse determination was HCSC Medical Policy: Immunoglobulin (Ig) Therapy (Including Intravenous [IVIG] and Subcutaneous Ig [SCIG]).

The specialty of the Medical Director that made the adverse determination was General Surgery.

The source of screening criteria utilized as guidelines in making this determination was Blue Cross and Blue Shield of Texas Medical Policy Guidelines, which are developed by the Blue Cross and Blue Shield of Texas Medical Division and which take into consideration views of the state and national medical communities, the guidelines and practices of Medicare, Medicaid, or other government-financed programs, and peer reviewed literature.

The sole purpose of this review is to assess whether the extended care meets the medical necessity requirements of the Benefit Plan.

This same information has also been sent to the servicing provider.

Please refer to the Appeal Information and Procedures and Appeal Request Form that are included with this letter for important appeal information.

This decision may be appealed to an Independent Review Organization (IRO), after you have completed BCBSTX internal appeal process. If your condition is life threatening, you may request an immediate review by an IRO. Please see attached IRO Notice and Adverse Determination Notice for procedure to obtain IRO Review.

If the member's benefit plan is governed by ERISA, the member or the member's authorized representative may have the right to take legal action under Sec. 502 (a) of ERISA if the benefit decision is upheld on appeal.

Thank you for your cooperation.
UM Utilization Management Department
Tollfree 1-800-441-9188 Local 972-783-4475
Tollfree Fax 1-866-221-3607

Blue Cross and Blue Shield of Texas
Attn: Utilization Management
P O Box 833874
Richardson, TX 75083-3874

cc: Robert J. Meador, MD
Central Line Infusion, LTD

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01/15/2014 9:18:44 AM AMERITA

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BlueCross BlueShield
of Texas

Subscriber Name: BRIAN TREADWELL
 Member Name: VIRGINIA TREADWELL
 Member Address: 5476 FM 2335
 CHRISTOVAL, TX 76935-3304
 Request ID: 13074AABLJ

March 20, 2013

Dear VIRGINIA TREADWELL:

This letter is in response to a request for service(s)/procedure(s). The following service(s)/procedure(s) has been approved as medically necessary as defined by the member's Health Care Benefits booklet or Summary Plan Description.

Member Name:	VIRGINIA TREADWELL
Date of Birth:	1971
Subscriber ID:	903574434
Request ID:	13074AABLJ
Physician:	ROBERT MEADOR
Facility/Provider:	CENTRAL LINE INFUSION LTD
Total Days/Units of Service:	870
Treatment Setting:	Home
Onset of Service:	MARCH-15-2013

Service Procedure Code/Description:	S9338 - HOME INFUSION THERAPY, IMMUNOTHERAPY, ADMINISTRATIVE SERVICES, PROFESSIONAL PHARMACY SERVICES, CARE COORDINATION, AND ALL NECESSARY SUPPLIES AND EQUIPMENT (DRUGS AND NURSING VISITS CODED SEPARATELY).	
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Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	42

Service Procedure Code/Description:	J1100 - INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1MG	
-------------------------------------	--	--

Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	410

Service Procedure Code/Description:	J7030 - INFUSION, NORMAL SALINE SOLUTION, 1000 CC	
-------------------------------------	---	--

Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	42

Service Procedure Code/Description:	99602 - Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure)	
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Effective Date	Expiration Date	Units Certified
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P.O. Box 833874 • Richardson, TX 75083-3874 • 1-800-441-9188 • www.bcbstx.com
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 March 20, 2013
 VIRGINIA TREADWELL
 903574434

3/15/2013	12/31/2013	124
Service Procedure Code/Description: 99601 - Home infusion/specialty drug administration, per visit (up to 2 hours);		
Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	42
Service Procedure Code/Description: J0171 - INJECTION, ADRENALIN, EPINEPHRINE, 0.1 MG		
Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	42
Service Procedure Code/Description: J2550 - INJECTION, PROMETHAZINE HCL, UP TO 50 MG		
Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	42
Service Procedure Code/Description: J1200 - INJECTION, DIPHENHYDRAMINE HCL, UP TO 50 MG		
Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	42
Service Procedure Code/Description: S9374 - HOME INFUSION THERAPY, HYDRATION THERAPY; ONE LITER PER DAY, ADMINISTRATIVE SERVICES, PROFESSIONAL PHARMACY SERVICES, CARE COORDINATION, AND ALL NECESSARY SUPPLIES AND EQUIPMENT (DRUGS AND NURSING		
Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	42
Service Procedure Code/Description: J1569 - INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), INTRAVENOUS, NON-LYOPHILIZED, (E.G. LIQUID), 500 MG		
Effective Date	Expiration Date	Units Certified
3/15/2013	12/31/2013	42

Please contact Blue Cross and Blue Shield of Texas at Phone Number: 1-800-441-9188 prior to the above listed expiration date if an additional review of benefits is needed for further days/units of service. In order to ensure coverage, Blue Cross and Blue Shield of Texas must also be notified if any of the following occur:

- The treatment plan or level of care is changed.
- The ordering physician or facility is changed from that noted above.
- The date of service is changed or cancelled.



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VIRGINIA TREADWELL
903574434

Approval through the Health Care Management Department is not a guarantee of payment of benefits. Payment of benefits is subject to several factors, including, but not limited to, eligibility at the time of service, payment of premiums/contributions, amounts allowable for services, supporting medical documentation and other terms, conditions, limitations and exclusions set forth in your Certificate of Benefits Booklet and/or Summary Plan Description as well as the preexisting condition waiting period, if any. For questions regarding benefits, please contact the Customer Service unit at the telephone number listed on the back of your health insurance card. You remain responsible for any out-of-pocket requirements, including, but not limited to, coinsurance, copayments, deductibles and/or non-covered charges.

Please note that, if you are receiving services through a non-contracting/non-participating provider (a provider with whom Blue Cross and Blue Shield of Texas does not have a contract/agreement, i.e. an out-of-network provider), you may be responsible for significant out-of-pocket costs for this service. The provider is not obligated to accept Blue Cross and Blue Shield of Texas allowance as payment in full. A non-contracting/non-participating provider may also charge you for any billed amount over the amount allowed for payment. If you need assistance finding a contracting/participating provider, i.e. an in-network provider, please call Customer Service at the number listed on your member identification card.

As always, the decision whether to receive the proposed service/procedure remains between you and your health care providers. Coverage, benefit and payment decisions do not constitute treatment decisions.

A copy of this information has also been sent to the provider/facility and physician.

Sincerely,

Blue Cross and Blue Shield of Texas
Health Care Services Department
Phone Number: 1-800-441-9188
Fax Number: 1-800-252-8815

CC: ROBERT MEADOR
601 CLARA BARTON
BLVD STE 300
GARLAND, TX 75042-5755

CENTRAL LINE INFUSION LTD
1301 SOUTH COULTER #201
AMARILLO, TX 79106



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Dec. 30. 2013 12:03PM Dallas Diagnostics (972) 494-5808

December 30, 2013
Page 1
Chart Document

Dallas Diagnostic Association - Garland
601 Clara Barton Blvd Suite 300 Garland, TX 75042
Phone: 469-800-2000 Fax: 972-272-2073

VIRGINIA TREADWELL Home: (512) 468-1971 Work: (325) 896-2405
Gender: Female DOB: Insurance: BCTX

12/20/2013 - Clinical Lists Update: Clinical List Update
Provider: Robert J Meador Jr MD
Location of Care: Dallas Diagnostic Association - Garland - Rheumatology

TO WHOM IT MAY CONCERN:

I would like to appeal the decision to provide IVIG for Virginia Treadwell.

She has severe Sjogren's Syndrome with autonomic neuropathy.

She has seen multiple specialists, including neurology, and tried many different therapies in the past.

It seems that only IVIG has significantly helped her autonomic neuropathy.

I am not the only physician who has recommended IVIG. I am also supported by Dr. Srikanth Muppidi at the Department of Neurology at UT HEALTH SCIENCE CENTER at SOUTHWESTERN who on 7/26/13 he wrote "I can justify continued usage of IVIG therapy."

She has tried and failed multiple therapies in the past, including phenergan, zofran, cyproheptadine, compazine, ativan, marnol, Pepcid, zantac, prilosec, nexium, medizine, ginger and Tigan. She has had postural orthostatic hypotension as a complication of this condition. She has tried and failed fludrocortisone as monotherapy.

Her Past Medical History includes
POTS

Gastroparesis

1. Clostridium difficile colitis.
2. Chronic abdominal pain and chronic pain syndrome.
3. Gastroparesis.
4. Postural orthostatic tachycardia syndrome.
5. Status post cholecystectomy.
6. Status post endoscopic retrograde cholangiopancreatography with repeat sphincteroplasty for ampullary stenosis.

Prior to IVIG, she was hospitalized multiple times for complications of Sjogren's Syndrome. I believe that IVIG has helped keep her out of the hospital, and so not only is she more productive and symptomatically improved on IVIG, I believe that it reduces overall cost of her care because it has reduced her need to be in the hospital.

There is experience with IVIG and Sjogren's as noted below. She has tried Plaquenil and is not a candidate for immunosuppressive therapy. Therefore, as this therapy has significantly helped her, please approve it without delay.

Experience of Intravenous Immunoglobulin Therapy in Neuropathy Associated With Primary Sjögren's Syndrome: A National, Multicentric Retrospective Study

Rist S, Sellam J, Hachulla E, et al.
Arthritis Care Res (Hoboken). 2011;63:1339-1344

Study Summary

Background. Peripheral and central neurologic disease may be clinical manifestations of primary Sjögren syndrome (SS). Mechanistically, SS-related

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Dec. 30. 2013 12:03PM Dallas Diagnostics (972) 494-5808

NO. 1121

December 30, 2013

Page 2

Chart Document

Dallas Diagnostic Association - Garland
 601 Clara Barton Blvd Suite 300 Garland, TX 75042
 Phone: 469-800-2000 Fax: 972-272-2073

VIRGINIA TREADWELL Home: (512) 468
 Gender: Female DOB: 1/1971

Work: (325) 896-2405
 Insurance: BCTX

neuropathy may be a consequence of vasculitis (more likely if motor neuropathy is present) or other less well-elucidated processes, such as autoantibody-mediated nerve dysfunction. [1] If vasculitis is the suspected cause of SS-related neuropathy, treatment typically entails potent immunosuppressive agents. Treatment for nonvasculitic SS-related neuropathy is less clear, although a variety of therapies, including corticosteroids and traditional immunosuppressive agents as well as plasmaphoresis and intravenous immunoglobulin (IVIg), have been reported in the literature. However, data to support the use of IVIg for the treatment of nonvasculitic neuropathy are limited; therefore Rist and associates sought to identify the efficacy and safety of IVIg in patients whose SS-related neuropathy was not caused by necrotizing vasculitis.

Methods. Questionnaires were mailed to 1400 French practitioners who were part of a participating network to identify patients with SS who had received ≥ 1 dose of IVIg for peripheral neuropathy. Through this mechanism, the investigators identified 19 patients with primary SS-related presumed nonnecrotizing vasculitic neuropathy who had been treated with IVIg. Outcomes of therapy were measured using the patient-completed Modified Rankin Score (MRS), which designates the degree of disability on the basis of symptoms and a global assessment by the care provider.

The mean age of the 19 patients was 60 years; 58% were women, and all fulfilled the American-European Consensus Group criteria for SS. [2] They had a variety of neuropathies classified as sensorimotor ($n = 5$), ataxic ($n = 9$), nonataxic sensory polyneuropathy ($n = 4$), and conduction block neuropathy ($n = 1$). Of note, ataxic neuropathy has been defined as impairment of position sense, with preserved muscle power and motor nerve function. [3] Six patients had nerve biopsies, with 5 showing nonnecrotizing leukocytoclastic vasculitis or lymphocytic infiltrates, and 1 biopsy was normal. The IVIg was typically administered in monthly infusions of 2 g/kg over either 2 or 5 days, and the median duration of IVIg treatment was 7 months (range 2-32 months) with follow-up ranging from 3 to 84 months. A variety of other immunosuppressive agents (steroids, cyclophosphamide, azathioprine, mycophenolate mofetil, hydroxychloroquine, and rituximab) were used either prior to or along with the IVIg.

Results, Conclusions, and Author Viewpoint

Results. The MRS improved in 8 patients. In 10 patients, the MRS was stable and in 1 patient MRS worsened. According to clinician assessment, all patients with sensorimotor, nonataxic sensory neuropathy and conduction block improved; however, of the 9 patients with ataxic neuropathy, only 2 improved, 4 worsened, and 3 remained stable. Ten of 13 patients who were treated with steroids were able to lower their doses, presumably as a result of the effects of IVIg. Only 1 patient discontinued IVIg because of an adverse effect (nausea), and no severe adverse effects such as thrombosis or renal failure were observed.

Conclusions. IVIg may be useful in treating patients whose SS-associated sensorimotor neuropathies are not caused by necrotizing vasculitis, although the benefit in patients with ataxic neuropathy appears to be reduced.

Viewpoint

These results suggest that IVIg may be useful in the treatment of some neuropathic manifestations of SS

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Dec. 30. 2013 12:04PM Dallas Diagnostics (972)494-5808

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601 Clara Barton Blvd Suite 300 Garland, TX 75042
Phone: 469-800-2000 Fax: 972-272-2073

December 30, 2013
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Chart Document

VIRGINIA TREADWELL Home: (512)468 Work: (325)896-2405
Gender: Female DOB: 1971 Insurance: BCTX

Also, another study below shows benefit with IVIG, as she also has features of small fiber neuropathy and there is evidence that IVIG helps this condition:

NCBINCB Logo
Skip to main content
Skip to navigation
Resources
How To
About NCBI Accesskeys
Sign in to NCBI
PubMed
US National Library of Medicine National Institutes of Health
Search database Search term Search
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Display Settings: Abstract Send to:
Mod Rheumatol. 2009;19(4):437-40. doi: 10.1007/s10165-009-0180-2. Epub 2009
May 22.
Extreme efficacy of intravenous immunoglobulin therapy for severe burning pain
in a patient with small fiber neuropathy associated with primary Sjögren's
syndrome.
Wakasugi D, Kato T, Gono T, Ito E, Nodera H, Kawaguchi Y, Yamanaka H, Hara M.
Author information

Abstract
Neurological involvement occurs in approximately 20% of patients with primary Sjögren's syndrome. Although neurological symptoms can affect the peripheral nervous system and the central nervous system, the most frequent symptom is polyneuropathy. Small fiber neuropathy (SFN) is a form of painful peripheral polyneuropathy that is common in patients with diabetic neuropathy, but may also occur in toxic, infectious, or immune-mediated neuropathy. We show here a patient with Sjögren's syndrome who developed SFN and was treated with intravenous immunoglobulin (IVIG) therapy, which was immediately and extremely effective. Because of the efficacy of IVIG therapy, we propose that direct immune-mediated mechanisms may be involved in the pathogenesis of SFN complicated by Sjögren's syndrome.

Sincerely,

Bobby

.....signed by: Robert J Meador
Jr MD December 20, 2013 3:28 PM

Electronically Signed by Robert J Meador Jr MD on 12/20/2013 at 3:32 PM



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JAN 15/2014 WED 04:32 PM SANANGELOHOMEHEALTH

FAX NO. 325 655 6602

1.001

CAUSE NO. D140013CVIRGINIA K. TREADWELL,
Plaintiff

vs.

BLUE CROSS AND BLUE
SHIELD OF TEXAS,
Defendant

IN THE DISTRICT COURT

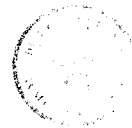
391st JUDICIAL DISTRICT

TOM GREEN COUNTY, TEXAS

AFFIDAVIT OF MECHELLE GRICE

Before me, the undersigned notary, on this day personally appeared, MECHELLE GRICE, a person whose identity is known to me. After I administered an oath to her, upon her oath she said:

1. "My name is MECHELLE GRICE. I am over 18 years of age, of sound mind, and capable of making this affidavit. The facts stated in this affidavit are within my personal knowledge and are true and correct.
2. "I am a Registered Nurse and work for San Angelo Home Health. Our address is 423 South Irving, Suite 1, San Angelo, TX 76903. Our phone number is (325) 655-6600 and our fax number is (325) 655-6602.
3. "I have known Virginia Treadwell since November, 2012. Mrs. Treadwell had previously been doing infusions at San Angelo Community Medical Center. In November, 2012, Mrs. Treadwell's doctor allowed her to have her infusions at home. At that time, NuFactor was the providing pharmacy for Mrs. Treadwell's IVIG. NuFactor would ship four weeks of IVIG to Mrs. Treadwell and then I, or another RN, from our agency would go to Mrs. Treadwell's house weekly to administer the IVIG. We would bill NuFactor and NuFactor would pay us. Then NuFactor would submit a claim to Blue Cross and Blue Shield of Texas to get paid. Last March, Mrs. Treadwell switched from NuFactor to Amerita. We have the same agreement and financial arrangement with Amerita that we did with NuFactor. Amerita ships the IVIG to Mrs. Treadwell four weeks at a time, and then we go to Mrs. Treadwell's house weekly to administer the IVIG.
4. "It was becoming increasingly more and more difficult to get IV access. We were spending hours at a time, one day doing 22 sticks, and using two RNs. Eventually, we used her feet. IN December 2012, our agency told Mrs. Treadwell we were not going to be able to continue to do her infusions without a port. So, in January, Mrs. Treadwell had a port implanted.
5. "In April 2013, we tried to decrease Mrs. Treadwell's IVIG to every other week. We were not able to maintain this because Mrs. Treadwell's symptoms increased. After one time, it was obvious it wasn't going to work.
6. "Mrs. Treadwell has been diagnosed with Sjogren's and Autonomic Neuropathy.



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FAX NO. 525 000 0504

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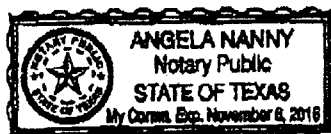
7. "Mrs. Treadwell has made significant improvements. Our nurses have observed, during the time spent in her home, decreased frequency of episodes of confusion; and when she has these episodes, they do not last as long; increased strength; increased stamina; decreased pain levels. Her blood pressure has become more normal. average blood pressure have improved as well. And her temperature is more often normal. When we began to see her it was more often elevated.

8. "This past month, Blue Cross and Blue Shield of Texas. I received a call from Dr. Meador's office saying BCBSTX was denying coverage and our orders were going to be on hold until the appeal was processed. I spoke with Amerita and let them know as well.

9. "Should you grant Mrs. Treadwell's Request for Temporary Restraining Order, we will be able to do an infusion for Mrs. Treadwell this week and next week as well."

Mechelle Grice
MECHELLE GRICE

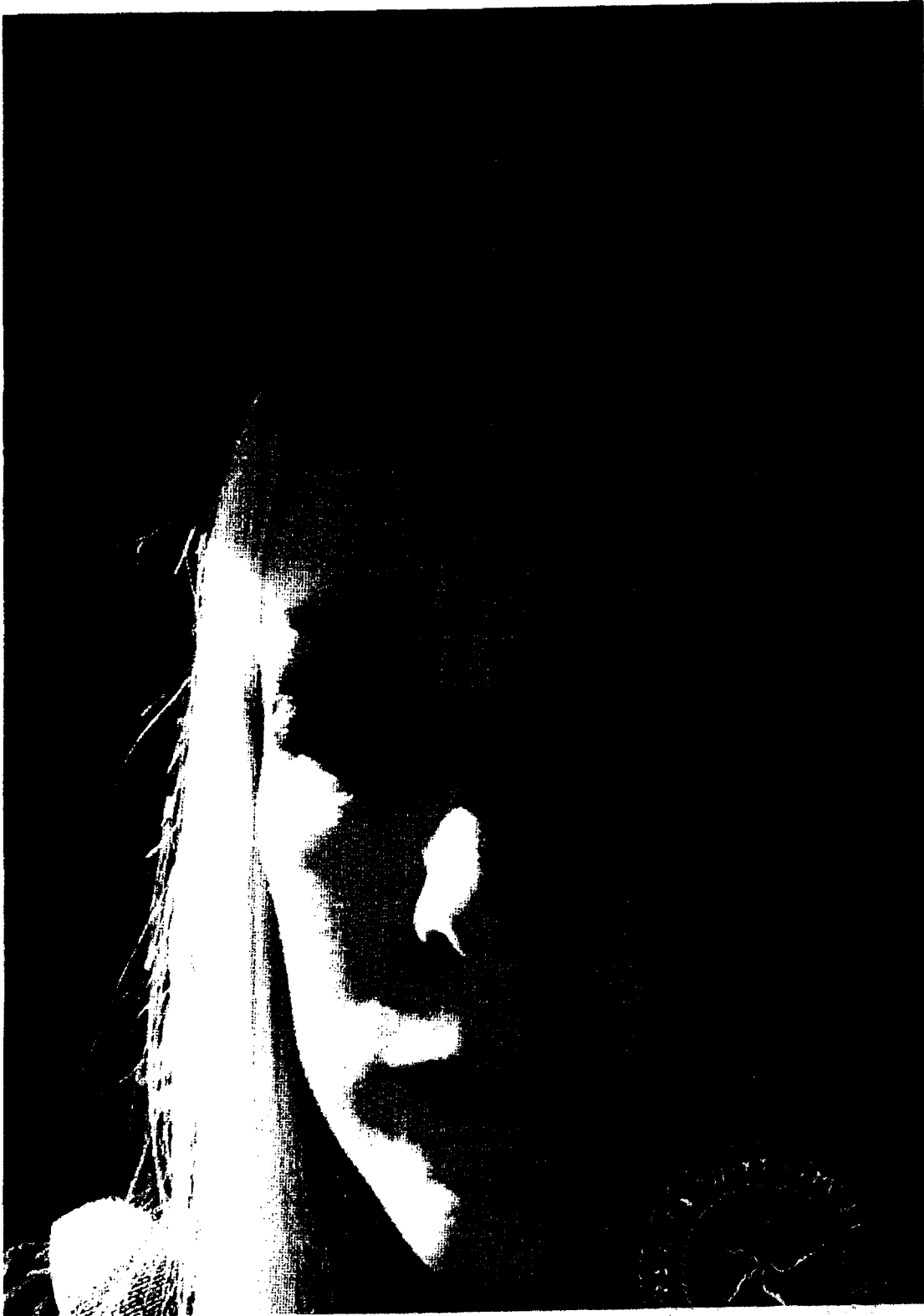
SIGNED under oath before me on Jan. 15, 2014.



Angela Nanny
Notary Public, State of Texas



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[A large, faint, diagonal line or signature mark spans across the upper half of the page.]

**VERIFIED COPY CERTIFICATE
STATE OF TEXAS COUNTY OF TOM GREEN**

I hereby certify that the above is a true and correct
copy of the original record on file in my office
Sherril Woodfin, District Clerk, Tom Green, Texas

JAN 23 2014

Attest:

By: *Melissa Salas*
Deputy

EXHIBIT 3

CAUSE NO. D140013L

VIRGINIA K. TREADWELL,
Plaintiff

vs.

BLUE CROSS AND BLUE
SHIELD OF TEXAS,
Defendant

§ IN THE DISTRICT COURT
§
§ 391st JUDICIAL DISTRICT
§
§
§ TOM GREEN COUNTY, TEXAS

TEMPORARY RESTRAINING ORDER

After considering Plaintiff Virginia Treadwell's verified Application for Temporary Restraining Order, the pleadings, the affidavits, and arguments of counsel, the court finds there is evidence that harm is imminent to plaintiff, and if the court does not issue the temporary restraining order, plaintiff will be irreparable injured in that

An ex parte order, without notice to defendant, is necessary because there was not enough time to give notice to defendant, hold a hearing, and issue a restraining order before the irreparable injury, loss or damage occurs.

Therefore, by this order, the court does the following:

1. Orders the Defendant, Blue Cross and Blue Shield of Texas, its agents, employees, servants and independent contractors to continue to provide Virginia Treadwell with the treatment and support which was provided until December 31, 2013, as per the most recent medications and physicians orders until further order of the court.

2. Orders the Defendant, Blue Cross and Blue Shield of Texas, its agents, employees, servants and independent contractors to refrain from cancelling the Plaintiff's insurance policy until the Defendant negotiates with Plaintiff in good faith and provides coverage for IVIG.

3. Orders the clerk to issue notice to Defendant, Blue Cross and Blue Shield of Texas, that the hearing on plaintiff's application for temporary injunction is set for JANUARY 27, 2014 at 2:00 a.m. (p.m.) The purpose of the hearing shall be to determine whether this temporary restraining order should be made a temporary injunction pending a full trial on the merits.

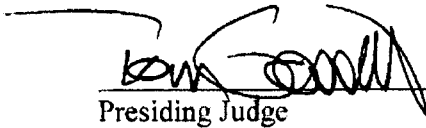
4. Sets bond at \$ 500,000.

This order expires on JANUARY 30, 2014.



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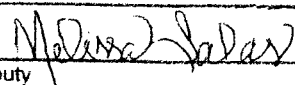
SIGNED ON JAN 16 2013, 2014, at 10:20 a.m./p.m.


Presiding Judge

COPY CERTIFICATE

STATE OF TEXAS COUNTY OF TOM GREEN

I hereby certify that the above is a true and correct copy of the original record on file in my office
Sheri Woodfin, District Clerk, Tom Green, Texas

Attest: _____
By: 
Deputy



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